

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

R E C E I V E D

ASTRAZENECA AB; AKTIEBOLAGET  
HÄSSLE; ASTRAZENECA LP; KBI INC.;  
and KBI-E INC.,

Plaintiffs and  
Counterclaim-Defendants,  
v.

HANMI USA, INC., HANMI  
PHARMACEUTICAL CO., LTD., HANMI  
FINE CHEMICAL CO., LTD, and HANMI  
HOLDINGS CO., LTD.,

Defendants and  
Counterclaim-Plaintiffs.

AT 8:30 WILLIAM T. WALSH<sup>M</sup>  
CLERK

JUN 15 2011  
Civil Action No. 3:11-CV-00760-JAP-TJB

Judge Joel A. Pisano  
Magistrate Judge Tonianne J. Bongiovanni

**STIPULATED DISCOVERY CONFIDENTIALITY ORDER**

Plaintiffs AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively “AstraZeneca”) and defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd. (“Hanmi”), by and through their undersigned counsel, hereby stipulate and agree that, in order to facilitate coordinated or consolidated discovery, the following discovery confidentiality order (“Order”) shall govern the use and handling of materials containing trade secrets and other confidential research, development and commercial information in the above captioned case, and request that the Court enter this stipulated Order in the above captioned case.

IT IS HEREBY AGREED AND ORDERED:

1. Designation Of Protected Material

- a. Any person or entity (the “Producing Party”) producing documents, things, information or other materials in the above captioned case (“Produced Material”) for inspection or review by another person or entity (the “Receiving Party”) may

designate as “Confidential” or “Attorney Confidential” pursuant to this Order any Produced Material that the Producing Party in good faith considers to be, reflect or reveal a trade secret or other confidential research, development or commercial information in accordance with Fed. R. Civ. P. 26(c)(1)(G), or other information required by law or agreement to be kept confidential.

b. A Producing Party may designate as “Confidential” pursuant to this Order any Produced Material that the Producing Party in good faith considers to be, reflect or reveal a trade secret or other confidential research, development or commercial information in accordance with Fed. R. Civ. P. 26(c)(1)(G), or other information required by law or agreement to be kept confidential.

c. A Producing Party may designate as “Attorney Confidential” pursuant to this Order any Produced Material that meets the requirements of Paragraph 1.b and also contains or comprises sensitive financial, marketing, customer, clinical, regulatory, research, development, scientific or commercial information, and which would likely prejudice or cause the Producing Party harm if disclosed to the technical employees of the Receiving Party.

d. All information designated as “Confidential” or “Attorney Confidential” including all copies, excerpts and summaries thereof, and all information contained therein or derived therefrom shall hereinafter be collectively referred to as “Protected Material.” Notwithstanding such designation, Protected Material does not include information that:

- (1) Was, is, or becomes public knowledge, not in violation of this Order;

- (2) Is acquired or was possessed by the Receiving Party in good faith without confidentiality restrictions or from a third party not subject to this Order;
- (3) Is discovered independently by the Receiving Party by means that do not constitute a violation of this Order; or
- (4) Was, is, or becomes expressly released from being designated as Protected Material by the Producing Party or by order of the Court.

2. Labeling Of Protected Material

a. The designation of Protected Material for purposes of this Order shall be made in the following manner:

- (1) With regard to written material (including transcripts of depositions or other testimony) and electronic images (such as TIFFs), a legend shall be affixed to each page substantially in the form, "Confidential" or "Attorney Confidential;" and
- (2) With regard to non-written material, such as recordings, magnetic media, photographs and things, a legend substantially in the above form shall be affixed to the material in any suitable manner.

b. Materials described in Paragraphs 2.a(1) and 2.a(2) made available by a Producing Party for inspection without confidentiality legends shall be deemed to be "Attorney Confidential" until otherwise designated by the Producing Party.

c. Deposition testimony taken in connection with this Proceeding temporarily will be designated as "Attorney Confidential" information for up to thirty (30) calendar days from both parties' receipt of a transcript of the deposition. Within thirty (30) calendar days of such receipt, parties and third parties must identify in writing to each of the parties hereto the portions of the transcript, by page number, that they wish

to designate as containing “Attorney Confidential” or “Confidential” information. A deponent may review the transcript of his or her deposition at any time.

The parties agree to mark the first page of all copies of deposition transcripts containing Confidential information with the legend “CONTAINS CONFIDENTIAL INFORMATION – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER.”

In the event that testimony adduced at a deposition contains or “Attorney Confidential” information, counsel for the designating party shall indicate which specific pages (or portions of pages) of the deposition transcripts contain “Attorney Confidential” material. The parties agree to mark the first page of the deposition transcript with the legend “CONTAINS ATTORNEY CONFIDENTIAL INFORMATION – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER.” That legend, however, will apply only to the specific pages (or portions of pages) that have been so designated.

3. Disclosure And Use Of Protected Material Absent an agreement of the Producing Party or an order to the contrary by this Court or other court of competent jurisdiction, a Receiving Party shall use Protected Material solely for purposes of litigating the above captioned case and not for any other purpose, including, without limitation, any business or commercial purpose, patent prosecution, a basis for judicial or administrative action, or correspondence with any government agency including the FDA. If a Receiving Party is served with a subpoena, discovery request in an action other than the above captioned case, or any other request seeking by legal process the production of Protected Material, such Receiving Party shall promptly notify the Producing Party, and inform the persons seeking discovery in writing (with copy to the Producing Party and the Court) that providing the Protected Material would be a violation of this Protective Order.

4. Qualified Persons A Receiving Party shall disclose Protected Material only to the following Qualified Persons, their clerical, support and secretarial staffs, paralegals and assistants. All rights, obligations and restrictions in this Order, including those set forth in, *e.g.*, Paragraph 3 above, shall apply to such Qualified Persons as if they were the Receiving Party. Qualified Persons under subparagraphs 4.b.(1) and 4.c.(1) are prohibited from any involvement with the prosecution of patents relating to esomeprazole for a period of one year following the conclusion of the above case, including all appeals.

Qualified Persons are:

- a. U.S. outside counsel of record in the above captioned case, and other attorneys working at their respective law firms (collectively, "Outside Counsel").
- b. For AstraZeneca:
  - (1) The following are Qualified Persons for all Protected Material (*i.e.*, "Confidential" and "Attorney Confidential"):

Marcus Heifetz  
William Krovin  
Denise Lacombe  
Thomas Stevens  
Raynard Yuro
  - (2) The following are Qualified Persons only for Protected Material designated as "Confidential" (*i.e.*, not "Attorney Confidential"):

Tommy Anderson  
Magnus Larsson  
Kurt Lövgren  
Staffan Schantz  
Sverker von Unge

c. For Hanmi:

- (1) The following are Qualified Persons for all Protected Material (*i.e.*, "Confidential" and "Attorney Confidential"):

Ms. Songhee Baik  
Hanmi Pharmaceutical  
45, Bani-dong, Songpa-gu, Seoul 138-724, Korea

Dr. C. Leon Kim  
Firstlaw Lee & Ko  
Seocho P.O. Box 437 26th Floor, Trust Tower, 275-7  
Yangjae-Dong Seocho-Ku, Seoul, 137-130, Korea

Mr. Jeong Ho Wi  
Firstlaw Lee & Ko  
Seocho P.O. Box 437 26th Floor, Trust Tower, 275-7  
Yangjae-Dong Seocho-Ku, Seoul, 137-130, Korea

(2) The following are Qualified Persons only for Protected Material designated as "Confidential" (*i.e.*, not "Attorney Confidential"):

Mr. Yushik Hwang  
Hanmi Pharmaceutical  
45, Bani-dong, Songpa-gu, Seoul 138-724, Korea

d. Experts and third-party technical service contractors who are not present employees of any party to the above captioned case, who are requested by Outside Counsel of the Receiving Party to furnish technical or expert services in connection with this litigation upon meeting the requirements of Paragraphs 6 and 7 of this Order.

e. Third-party contractors involved solely in providing litigation support services to Outside Counsel, including but not limited to independent litigation support service personnel, copying services, translation services, imaging services and coding services.

f. The Court and its personnel.

g. An officer or other person before whom a deposition is taken in the above captioned case, including any stenographic reporter or videographer.

h. Any other person agreed to by the parties to the above captioned case or allowed by the Court.

5. Restrictions Not Imposed By This Order

a. This Order shall not restrict any Producing Party's use, for any purpose, of its own Protected Material.

b. This Order shall not restrict any counsel who is a Qualified Person from rendering advice to the party it represents in the above captioned case, and in the course thereof, from generally relying upon his or her examination of Protected Material. In rendering such advice, the attorney shall not disclose directly or indirectly the content of any Protected Material where such disclosure would not otherwise be permitted under the terms of this Order.

6. Notice And Acknowledgement Of Order

a. Every Qualified Person to whom Protected Material or information contained therein is to be disclosed, summarized, described, characterized, or otherwise communicated or made available in whole or in part, first shall be advised that the material or information is being disclosed pursuant and subject to the terms of this Order.

b. Before any disclosure of Protected Material is made to a Qualified Person pursuant to Paragraphs 4.b, 4.c, 4.d or 4.h, Outside Counsel for the Receiving Party shall: (a) provide the Qualified Person with a copy of this Protective Order; (b) explain its terms; and (c) obtain the Qualified Person's written agreement, in the form of Exhibit A hereto, to comply with and be bound by its terms. All Qualified Persons to whom disclosure of Protected Material is intended shall confirm their understanding and agreement to abide by the terms of this Order by signing a copy of the acknowledgement attached as Exhibit A.

7. Notification Of Intent To Disclose And Objections

a. Before Protected Material is disclosed to a Qualified Person under Paragraphs 4.b, 4.c, 4.d or 4.h, the Receiving Party shall, at least five business days prior to such disclosure, notify the Producing Party in writing by electronic mail, of its intent to disclose Protected Material. Such notification shall include the name, current address, and employment affiliation (including job title, if any) of the Qualified Person to whom such disclosure is proposed. The notification shall also include a copy of the signed acknowledgement made in conformance with Paragraph 6 of this Order. With respect to Qualified Persons listed in Paragraph 4.d, the notification shall further include a current resume or curriculum vitae from the person.

b. The notification and signed acknowledgement shall be made in writing and delivered by electronic mail to:

Errol Taylor  
Milbank, Tweed, Hadley & McCloy LLP  
1 Chase Manhattan Plaza  
New York, NY 10005  
etaylor@milbank.com

Henry J. Renk  
Fitzpatrick, Cella, Harper & Scinto  
1290 Avenue of the Americas  
New York, NY 10104-3800  
hrenk@fchs.com

Mark Boland  
Sughrue Mion, PLLC  
2100 Pennsylvania Ave., NW  
Washington D.C. 20037  
mboland@sughrue.com

c. If a Producing Party receiving a notification of intent to disclose Protected Material believes in good faith that such disclosure of Protected Material would be injurious or prejudicial, it may object to the proposed disclosure by giving written notice

be electronic mail of such objection to the Receiving Party seeking to make the disclosure. Such notice shall include the basis for the objection and shall be delivered in accordance with Paragraph 7.a and 7.b within five business days of receipt of the notification of intent to disclose to which objection is made. If the Producing Party objects, the proposed disclosure shall not take place until the objection is resolved by agreement of the Producing Party or order of this Court. Failure to object within the time period set forth above shall be deemed a consent. If the objection cannot be resolved, either party may seek relief from the Court but the Producing Party shall have the burden of proof that the intended disclosure should not occur.

d. Any party may seek to substitute another in-house attorney for an attorney listed in Paragraphs 4.b or 4.c by following the procedures described in Paragraphs 7.a, 7.b, and 7.c. Any party may seek to add in-house non-attorney scientific advisors to the list of individuals permitted access under Paragraphs 4.b(1) or 4.c(1) by notifying the parties that the individual will have access to all Protected Material and by following the procedures identified in Paragraphs 7.a, 7.b and 7.c. Any party may seek to add in-house non-attorney scientific advisors to the list of individuals permitted access under paragraphs 4.b(2) or 4.c(2) by notifying the parties that the individual will have access only to Protected Material designated as Confidential and by following the procedures identified in Paragraphs 7.a, 7.b and 7.c.

8. Examination Of Witnesses at Deposition Protected Material may be disclosed to a witness and its counsel at a deposition (a) if the witness is an officer, director, or employee of the party who produced such Protected Material; (b) if the witness was formerly an officer, director, or employee of the party who produced such Protected Material, and the Protected Material existed during the period of his or her service or employment; (c) if the Protected Material was authored by, created by, addressed to, received by, signed by the witness; or (d) if the witness is a designee for the Producing Party under Federal Rule 30(b)(6) concerning any topic to which the Protected Material is relevant; or (e) the parties otherwise agree.

9. Inadvertent Production Of Privileged Or Protected Material

a. If information subject to a claim of attorney-client privilege, attorney work product immunity or any other legal privilege protecting information from discovery is inadvertently produced, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege, work product immunity or other ground for withholding production to which the Producing Party or other person otherwise would be entitled, provided that the Producing Party identifies in writing that the inadvertently produced material is subject to a claim of immunity or privilege within ten (10) calendar days of discovery of the inadvertent production or within ten (10) calendar days of receiving notice from another party of potential inadvertent production. Upon a written claim of inadvertent production, the Receiving Party having custody of the inadvertently produced material shall return to the Producing Party that material and all copies or reproductions thereof of which that Receiving Party is aware in whatever form these materials exist, and that information may not be used for any purpose. The Receiving Party may subsequently move the Court for an Order compelling production of the material, but such motion shall not disclose the substance of the inadvertently

produced material except to the extent that an *in camera* inspection of the materials may be requested.

b. Inadvertent failure to designate any material which a Producing Party claims should be Protected Material will not be deemed a waiver of the right to make that designation. Upon receiving notice of such failure to designate, all Receiving Parties shall cooperate to restore the confidentiality of the inadvertently or unintentionally disclosed Produced Material. No party shall be held in breach of this Order if, prior to notification of such later designation, such Produced Material had been disclosed or used in a manner inconsistent with such later designation. The Producing Party shall provide substitute copies bearing the corrected designation. The Receiving Parties shall return or certify the destruction of the undesignated Produced Material.

10. Obligations of Outside Counsel It shall be the responsibility of Outside Counsel to ensure strict compliance with the provisions of this Order and to take reasonable and proper steps to ensure that all provisions thereof are made known to any person who shall examine Protected Material.

11. Filing of Protected Material

a. A party seeking to file any documents or things containing “Confidential” or “Attorney Confidential” information shall file a motion to seal, or otherwise restrict public access to, those materials pursuant to Local Civil Rule 5.3(c). All documents and things deemed “Confidential” or “Attorney Confidential” submitted with regard to a motion to seal shall be filed under the designation “confidential materials” and shall remain sealed until such time as the motion is decided.

(1) The burden of proving to the Court that such material designated as “Confidential” or “Attorney Confidential” should be sealed under Local Civil

Rule 5.3 shall at all times remain with the party that initially produced the material and designated it as "Confidential" or "Attorney Confidential" (hereinafter, "the Designating Party") and the Designating Party shall be responsible for filing supplemental motion papers pursuant to Local Civil Rule 5.3(c)(2), and

(2) If the party filing the material is not the Designating Party, the filing party nonetheless is obligated to make a reasonable effort when filing material designated as "Confidential" or "Attorney Confidential" to meet the provisions of Local Civil Rule 5.3 to protect the Designating Party's materials.

12. Conclusion of the Action Within sixty (60) days after entry of a final judgment or dismissal with prejudice (including appeals or petitions for review) or the execution of a settlement agreement, finally disposing of all issues raised in the above captioned case, all Receiving Parties no longer in such case(s) shall: (a) return all Protected Material and any copies thereof to the appropriate Outside Counsel who produced the Protected Material; or (b) destroy such Protected Material. Each Receiving Party shall give written notice of such destruction to Outside Counsel for the Producing Party. However, Outside Counsel who are trial counsel may retain one copy of all pleadings for archival purposes. Further, all notes, summaries, or other documents prepared by Qualified Persons under Paragraphs 4.b, 4.c, 4.d and 4.h, derived from or containing Protected Material, shall after the conclusion of the action, be kept within the files of Outside Counsel who are trial counsel for the Receiving Party creating such work product, or be destroyed.

13. Contested Designations A Receiving Party shall not be obligated to challenge the propriety of a Producing Party's designations of any Protected Material at the time such designation is made, and failure to do so shall not preclude a subsequent challenge thereto. If the

Receiving Party disagrees with the designation of any Protected Material, the Receiving Party may, after holding a meeting with the Producing Party, make a request of the Court for an order removing such Protected Material from the restrictions of this Protective Order.

14. Non-Waiver The production of Produced Material under the terms of this Order in response to a request by an opposing party shall not be construed to mean that the Producing Party has waived any objection to the production, relevancy or admissibility of said Produced Material. Nothing contained herein shall preclude any party from opposing any discovery on any basis. Further, nothing in this Order constitutes an admission by any party that any specific item of Protected Material is a trade secret or otherwise confidential and proprietary to a party.

15. Additional Parties If an additional party joins or is joined in the above captioned case, the newly joined party shall not have access to Protected Material until all parties to the above captioned case agree to a supplemental Discovery Confidentiality Order governing the protection of Protected Material.

16. Third Parties Any third party from whom discovery is sought in the above captioned case may, in accordance with this Order, designate some or all of its production as Protected Material, and each Receiving Party will have the same rights, obligations and restrictions which that Receiving Party has with respect to the Protected Material of any other Producing Party.

17. Attendance At Proceedings If a deposition concerns Protected Material, the Producing Party shall have the right to exclude from the portion of the deposition concerning such information any person not authorized in accordance with Paragraph 4 hereof to have access to such material. All persons not authorized in accordance with Paragraph 4 hereof for access to Protected Material may be excluded from the trial and any hearings and conferences in this action.

18. Unauthorized Disclosure In the event of disclosure of any Protected Material to a person not authorized to have access to such material, the party responsible for having made, and any party with knowledge of, such disclosure shall immediately inform Outside Counsel for the party whose Protected Material has thus been disclosed of all known relevant information concerning the nature and circumstances of the disclosure. The responsible party shall also promptly take all reasonable measures to ensure that no further or greater unauthorized disclosure or use of such information or materials is made. Each party shall cooperate in good faith in that effort.

19. Termination Of Access

a. In the event that any person or party ceases to be engaged in the conduct of this action, such person's or party's access to Protected Material shall be terminated, and all copies thereof shall be returned or destroyed in accordance with the terms of Paragraph 12 hereof, except that such return or destruction shall take place as soon as practicable after such person or party ceases to be engaged in the conduct of this action.

b. The provisions of this Order shall remain in full force and effect as to any person or party who previously had access to Protected Material, except as may be specifically ordered by the Court or consented to by the Producing Party.

20. Production Prior To This Order Absent an agreement of the Producing Party or an order to the contrary by this Court or other court of competent jurisdiction-a Receiving Party shall use Documents or things produced in this action prior to entry of this Order solely for purposes of litigating the above captioned case and not for any other purpose, including, without limitation, any business or commercial purpose, patent prosecution, a basis for any judicial or administrative action, or correspondence with any government agency including the FDA. Documents or things produced in this action prior to entry of this Order and subject to

confidentiality restrictions shall be redesignated by each Producing Party within 30 days of the entry of this Order in accordance with Paragraph 2 hereof, to the extent not already appropriately designated "Confidential" or "Attorney Confidential." Until such time as the documents and things are redesignated (pursuant to this paragraph or otherwise), all documents or things produced prior to the date of this Order will be for outside counsel's Attorney's eyes Only and shall be treated in accordance with Local Patent Rule 2.2.

21. Modification Stipulations may be made, between Counsel for the respective parties, as to the application of this Order to specific situations, provided that such stipulations are recorded in writing or contained in the record of any oral proceeding. Nothing contained herein shall preclude any party from seeking an order of the Court modifying or supplementing this Order.

Dated: \_\_\_\_\_

Dated: \_\_\_\_\_

By: \_\_\_\_\_

John E. Flaherty  
McCARTER & ENGLISH  
Four Gateway Center  
100 Mulberry Street  
Newark, New Jersey 07102  
(973) 622-4444  
jflaherty@mccarter.com

*Of Counsel:*

Errol B. Taylor  
Fredrick M. Zullow  
MILBANK, TWEED, HADLEY &  
McCLOY LLP  
1 Chase Manhattan Plaza  
New York, New York 10005-1413  
(212) 530-5000  
etaylor@milbank.com  
fzullow@milbank.com

Henry J. Renk  
Bruce C. Haas  
FITZPATRICK, CELLA, HARPER &  
SCINTO  
1290 Avenue of the Americas  
New York, NY 10104-3800  
(212) 218-2250  
hrenk@fchs.com  
bhaas@fchs.com

*Attorneys for Plaintiffs and Counterclaim-Defendants,*  
AstraZeneca AB, Aktiebolaget Hässle,  
AstraZeneca LP, KBI Inc., and KBI-E Inc.

By: \_\_\_\_\_

Allyn Z. Lite  
Michael E. Patunas  
Mayra V. Tarantino  
LITE DEPALMA GREENBERG, LLC  
Two Gateway Center, 12th Floor  
Newark, New Jersey 07102  
(973) 623-3000  
alite@litedepalma.com  
mpatunas@litedepalma.com  
mtarantino@litedepalma.com

*Of Counsel:*

Mark Boland  
Michael R. Dzwonczyk  
Renita S. Rathinam  
SUGHRUE MION, PLLC  
2100 Pennsylvania Ave., NW  
Washington, DC 20037-3213  
(202) 253-4903  
mboland@sughrue.com  
mdzwonczyk@sughrue.com  
rrathinam@sughrue.com

*Attorneys for Defendants and Counterclaim-Plaintiffs,*  
Hanmi USA, Inc., Hanmi Pharmaceutical  
Co., Ltd., Hanmi Fine Chemical Co., Ltd.,  
and Hanmi Holdings Co., Ltd.

SO ORDERED:

Dated: June 15, 2011

  
Honorable Tonianne J. Bongiovanni  
United States Magistrate Judge

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## **EXHIBIT A**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

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ASTRAZENECA AB; AKTIEBOLAGET  
HÄSSLE; ASTRAZENECA LP; KBI INC.;  
and KBI-E INC.,

Plaintiffs and  
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HANMI USA, INC., HANMI  
PHARMACEUTICAL CO., LTD., HANMI  
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HOLDINGS CO., LTD.

Civil Action No. 3:11-CV-00760-JAP-TJB

Judge Joel A. Pisano  
Magistrate Judge Tonianne J. Bongiovanni

Defendants and  
Counterclaim-Plaintiffs.

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**ACKNOWLEDGEMENT TO ABIDE BY THE PROTECTIVE ORDER**

I, \_\_\_\_\_, declare that:

1. I have read the foregoing Protective Order entered as an Order of the United States District Court for the District of New Jersey, in the action entitled *AstraZeneca AB et al. v. Hanmi USA, Inc. et al.*, Civil Action No. 11-CV-00760 (JAP)(TJB).
2. I understand and agree to be bound by the terms of this Protective Order.
3. I will hold in confidence and will not disclose to anyone who is not a Qualified Person under the Protective Order and will use only for purposes of this action, any Protected Material disclosed to me.
4. I will return all Protected Material that comes into my possession, and documents or things that I have prepared relating thereto, to counsel for the party by whom I am employed or retained when requested to do so by that counsel.

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5. I hereby submit to the jurisdiction of this Court for the purpose of enforcement of this Protective Order.

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(Signature)

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(Printed Name)

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(Date)